K121925

Suzhou Colour-way Enterprise Development Co., Ltd

83 Changping Road, Dongqiao Industrial Area, 215152, Suzhou, Jiangsu PRC
TEL: 86-512-65371793; FAX: 86-512-65379978; E-mail: zhuyingqiu@hotmail.com

510(k) Summary

The assigned 510(k): K121925

1. Submitter

Name:	Suzhou Colour-way Enterprise Development Co., Ltd
Address:	83 Changping Road, Dongqiao Industrial Area, 215152, Suzhou, Jiangsu, China
TEL:	86-512-65371793
FAX:	86-512-65379978

Date summary prepared: June 14, 2013

2. Contact person

AUG 2 8 2013

Name:	Miss Zhu Yingqiu
TEL:	86-512-65371793
FAX:	86-512-65379978
E-mail:	zhuyingqiu@hotmail.com

3. Device Identification

Trade name: Powdered Latex Surgeon's Glove
Common name: Surgeon's glove
Classification name: Surgeon's glove
Classification number: KGO, class I
Regulation number: 21CFR 878.4460

4. Identification of the Predicate device

Trade name:	Powdered Latex Surgeon's Glove
510(k) number:	K062797
Product code:	KGO

5. Description of the Device

The glove is made of natural rubber latex. It is powdered with absorbable dusting powder. The sterility status is sterile. It meets all the requirements of ASTM D3577-09$^{\varepsilon 1}$. No colorant is added during manufacture of our Powdered Latex Surgeon's Glove. The color of our glove is ivory.

6. Directions for use:

The product is made of natural rubber latex which may cause allergic reactions. It is powdered with absorbable dusting powder. The Powdered Latex Surgeon's Glove is sterilized by radiation. It is single use only, and can not be reused. Don't use if the package is damaged.

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7. Indications for Use:

This Powdered Latex Surgeon's Glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

8. Summary of the technological characteristics of the device compared to the predicate device

Characteristics		**New Device Colour-way's Glove**	**Predicate Device Powdered Latex Surgeon's Glove (K062797)**
Material Composition		Natural Rubber Latex	Natural Rubber Latex
Colorant		No colorant	No colorant
Design		Single use Sterile Powdered Beaded Cuff	Single use Sterile Powdered Beaded Cuff
Indications for Use		This Powdered Latex Surgeon's Glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.	This Powdered Latex Surgical Glove is a disposable device made of natural rubber latex material that bears powder to facilitate donning, and it is intended to be worn on the hands, usually in surgical setting, to provide a barrier against potentially infectious materials and other contaminants.
Length	5.5	250~280 mm	Min.245 mm
	6	260~290 mm	Min.265 mm
	6.5	260~290 mm	Min.265 mm
	7	270~300 mm	Min.265 mm
	7.5	270~300 mm	Min.265 mm
	8	270~300 mm	Min.265 mm
	8.5	280~310 mm	Min.265 mm
	9	280~310 mm	Min.265 mm
Width	5.5	72±4 mm	70±6 mm
	6	77±5 mm	76±6 mm
	6.5	83±5 mm	83±6 mm
	7	89±5 mm	89±6 mm

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Characteristics		New Device Colour-way's Glove	Predicate Device Powdered Latex Surgeon's Glove (K062797)
	7.5	95±5 mm	95±6 mm
	8	102±6 mm	102±6 mm
	8.5	108±6 mm	108±6 mm
	9	114±6 mm	114±6 mm
Thickness	Cuff	0.21±0.1 mm	Min. 0.10 mm
	Palm	0.24±0.1 mm	Min.0.10 mm
	Finger	0.25±0.1 mm	Min.0.10 mm
Before Ageing	Tensile Strength	33~38 MPa	24MPa, min
	Ultimate Elongation	750~800%	750% min
	Stress at 500% Elongation	5.2~5.4MPa	5.5MPa, max
After Ageing	Tensile Strength	28~34 MPa	18 MPa, min
	Ultimate Elongation	740~810%	560%, min
Water Leak		Inspection Level: I AQL: 1.5	Inspection Level: I AQL: 1.5
Biocompatibility	Guinea Pig Maximization	Gloves showed no significant evidence of causing skin sensitization as per ISO10993-10.	Gloves showed no significant evidence of causing skin sensitization.
	Primary Skin Irritation	Gloves are not irritating as per ISO10993-10.	Gloves are not irritating.
Sterilization validation		Meet acceptance criteria as per ISO 11137-2.	Meet acceptance criteria
Labeling Features		Include the required labeling: Surgeon's Gloves, Sterile, Disposable,	Include the required labeling: Surgeon's Gloves, Sterile, Disposable, Powdered,

Characteristics	New Device Colour-way's Glove	Predicate Device Powdered Latex Surgeon's Glove (K062797)
	Powdered Natural rubber latex allergy warning, Name and Place of Business, Country of Origin, etc	Natural rubber latex allergy warning, Name and Place of Business, Country of Origin, etc

Based on the above comparison, the Colour-way Powdered Latex Surgeon's Glove is equivalent to the predicate device with respect to technology characteristics such as material, design, intended use, specification and performance features. It is as safe and effective and performed as well as the referenced predicate device.

9. Clinical Data

Not Applicable

10. Conclusions

The Powdered Latex Surgeon's Glove manufactured by Suzhou Colour-way Enterprise Development Co., Ltd and the predicate device meet the technology characteristics of ASTM D3577-09$^{\epsilon 1}$, ISO10993-10:2010 and ISO11137-2:2012 standards. Besides, our Powdered Latex Surgeon's Glove contains no more than 15mg/dm^2 powder and no more than 200μg/dm^2 extractable protein. Consequently, the device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Suzhou Colour-Way Enterprise Development Company, Limited
Ms. Zhu Yingqiu
83 Changping Road
Dongqiao Industrial Area
Suzhou, Jiangsu
PR China 215152

Re: K121925
Trade/Device Name: Powdered Latex Surgeon's Glove
Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 21, 2013
Received: August 26, 2013

Dear Ms. Yingqiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) Number (if known): K121925
Device Name: Powdered Latex Surgeon's Glove
Indications For Use: This Powdered Latex Surgeon's Glove is a disposable device made of natural rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use_____ AND/OR Over-The-Counter Use ____X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Sreekanth Gutala -S
2013.08.28 12:05:22 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121925